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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,825	08/30/2002	Todd M Upton	C1005/7009	5262

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,825	Applicant(s) UPTON ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 14, 15, 23, 28, 38, 49, 53, 55, 56, 62 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23, 28, 38 and 49 is/are allowed.
- 6) ☒ Claim(s) 1-5, 14, 15, 53, 55, 56, 62, 77 and 78 is/are rejected.
- 7) ☒ Claim(s) 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 15, 16, 53 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Satake (JP 02-280823).

With respect to claims 1, 53, 77 and 78, the reference of Satake discloses a bioreactor that includes a vessel (4) for holding a liquid culture media; a matrix assembly mounted in the vessel (4) for movement in the media, the matrix assembly including a support (2) and a plurality of three-dimensional porous matrix members (1) carried by the support for movement therewith; and a drive member(W) operatively coupled to the support for moving it with the matrix members through the media. Note porous matrix members are rigid and of unitary structure.

With respect to claim 2, the support includes a shaft (2); an outwardly extending member (4, see Figure 5) connected to the shaft (2) and a holder (5) for carrying at least one three-dimensional porous matrix member (1) and mounted on the outwardly extending member (4,5).

With respect to claim 3, the holder (5) is removably attached to the outwardly extending member (4).

With respect to claim 5, the holder (5) supports plural matrix members (1).

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With respect to claims 15 and 55, see the discussion of claims 2 above. Also, the reference of Sakate discloses that shaft (2) is disposed in the vessel (4) and supported for rotation by a cover (See Figure 2).

3. Claims 1-4, 14, 15, 53, 55, 77 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Oishi (JP 02-42974).

With respect to claims 1, 53, 77 and 78, the reference of Oishi discloses a bioreactor (1) that includes a vessel (1) for holding a liquid culture media; a matrix assembly mounted in the vessel (1) for movement in the media, the matrix assembly including a support (5) and at least one rigid three dimensional porous solid matrix member (6), which is a unitary structure, carried by the support for movement therewith; and a drive member (4) operatively coupled to the support for moving it with the matrix members through the media.

With respect to claims 2 and 4, the support includes a shaft (5) and outwardly extending member (shown in Figure 2) connected to the shaft and holders (7a, 7b).

With respect to claim 3, the holders (7a, 7b) are inherently removable from the outwardly extending members.

With respect to claims 14, 15 and 55, the vessel includes a cover supporting shaft (5) (See Figure 2).

4. Claims 1-4, 53, 62, 77 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hitachi (JP 04-126068).

With respect to claims 1 and 53, the reference of Hitachi discloses a bioreactor that includes a vessel (12) for holding a liquid culture media; a matrix assembly (13) mounted in the vessel (12) for movement in the media, the matrix assembly (13) including a support (See Figure 5) and a plurality of three-dimensional porous matrix members (20) carried by the support for movement therewith; and a drive member (56, 58, 60, 62) operatively coupled to the support for moving it with the matrix members through the media.

With respect to claims 2, 77 and 78, the support includes a shaft (14); an outwardly extending member (See Figure 5) connected to the shaft (14) and a holder (See o-ring in Figure 5) for carrying at least one three-dimensional porous matrix member (20) and mounted on the outwardly extending member (See Figure 5).

With respect to claim 3, the holder (See o-ring in Figure 5) is removably attached to the outwardly extending member.

With respect to claim 4, the outwardly extending member carries a plurality of holders (See Figure 2).

With respect to claim 62, the device as disclosed by the reference of Hitachi is used for in vitro cell culture (See the English language abstract).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-5, 14-16, 53, 55, 56, 62, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuriyama (US 5,728,577) in view of Hitachi (JP 04-126068) or Schenck (US 6,245,236).

With respect to claims 1 and 53, the reference of Kuriyama discloses a bioreactor (1) that includes a vessel (4) for holding a liquid culture media; a matrix assembly (32) mounted in the vessel (4) for movement in the media, the matrix assembly (32) including a support (33) and a plurality of three-dimensional porous matrix members (23) carried by the support for movement

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therewith; and a drive member (15) operatively coupled to the support for moving it with the matrix members through the media.

While the reference of Kuriyama discloses the use of three-dimensional porous matrix members of a unitary structure (see column 4, lines 52-66, "The porous materials for the carrier body 23 may be soft material such as open-cell foam rubber foam, nonwoven fabric and polypropylene fiber"), the instant claims differ by reciting that the matrix members are rigid and solid members.

The references of Hitachi and Schenck both disclose that it is known in the art of bioreactors to employ porous cell carriers that are made of rigid solid porous materials (See porous carrier (20) of Hitachi and porous carrier (46) of Schenck).

In view of either of these teachings and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a rigid solid porous material for the carriers in the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result. Note, using a rigid and solid porous carrier would eliminate the need for frame or support members (24,25) required when using non-rigid support as disclosed by the reference of Kuriyama.

With respect to claims 2, 77 and 78, the support includes a shaft (16,33); an outwardly extending member (34 or 35) connected to the shaft (16, 33) and a holder (22,24,25) for carrying at least one three-dimensional porous matrix member (23) and mounted on the outwardly extending member (34 or 35).

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With respect to claim 3, the holder (22, 24, 25) is removably attached to the outwardly extending member (See column 4, lines 41-51).

With respect to claim 4, the outwardly extending member carries a plurality of holders (22, 24, 25) (See Figure 1).

With respect to claim 5, the holder (22) can be filled with a plurality of porous particles (See column 5, lines 6-24).

With respect to claims 14, 15 and 55, see the discussion of claims 2 and 4 above. Also, the reference of Kuriyama discloses that shaft (16) is disposed in the vessel (4) and supported for rotation by cover (14).

With respect to claim 56, the holder (22, 24, 25) include means (36) for mounting the holder to the support; engaging means (25B) for carrying a three-dimensional porous matrix (23); and a three-dimensional porous matrix (23) attached to the holder by the engaging means.

With respect to claim 62, the device as disclosed by the reference of Kuriyama is used for in vitro cell culture (See column 1, lines 5-15).

Allowable Subject Matter

9. Claims 23, 28, 38 and 49 are allowed.

10. Claim 79 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. The following is a statement of reasons for the indication of allowable subject matter:

Claims 23, 28, 38, 49 and 79 are allowable because the prior art of record fails to disclose the combination of elements as recited in these claims, especially the presence of a groove in each of the arms of the "U"-shaped holder for removably holding a three-dimensional porous matrix member and/or the presence of a closure-cap detachably mounted on the open end of the "U"-shaped holder wherein the cap prevents the porous matrix member from being withdrawn from the holder and includes a handle for removing the cap from the holder and for carrying the assembly without touching the matrix members in the holder.

Response to Arguments

12. Applicant's arguments filed 10 June 2004 have been fully considered but they are not persuasive.

With respect to the rejection of the claims over the reference of Kuriyama, Applicants argue that the rejection is no longer applicable in view of the amendments to the claims that require that the claimed devices include "at least one rigid three-dimensional porous solid matrix member".

In response, the rejections of record over the reference of Kuriyama have been modified to address the obviousness of the newly recited claim limitations.

With respect to the rejection of the claims over the reference of Hitachi, Applicants argue that the rejection is no longer applicable in view of the amendments to the claims that require that the claimed devices include "at least one rigid three-dimensional porous solid matrix

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member". Applicants stress that the structure disclosed by the reference of Hitachi as shown in Figure 3 encompasses a perforated plate that supports beads.

In response, Applicants' comments are not found to be persuasive because the Examiner maintains that the members (20) disclosed by the reference are rigid solid porous plates that support cell growth and meet the language of the instant claims in terms of the matrix member. Note Figure 3 appears to show the pores and cells within the pores of the porous member rather than the beads as advanced by Applicants. Note the English language abstract recites porous plates and is silent as to the use of "beads" held within a container structure.

Applicants' amendments to the claims and associated comments are persuasive to overcome the prior art rejection of record that includes the reference of Krovak.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB